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Panel on Health Services

Updated background brief prepared by the Legislative Council Secretariat for the special meeting on 23 December 2013

Regulation of medical beauty treatments/procedures

Purpose

This paper gives an account of the past discussions of the Panel on Health Services ("the Panel") on issues relating to the regulation of medical beauty treatments or procedures.

Background

2. In early October 2012, there were four reported cases of women suffering from septic shock after receiving intravascular infusions at a beauty treatment centre. One woman subsequently died of multiple organ failure while the other three were seriously ill. The incident has aroused public concerns over the need for the Government to tighten up regulation of the beauty industry and provide a clear definition to differentiate beauty therapies from medical procedures.

3. Meanwhile, the Administration established a Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee") in October 2012 to review the regulatory regime for private healthcare facilities. A Working Group on Differentiation between Medical Procedures and Beauty Services ("the Working Group") was set up under the Steering Committee in November 2012. The Working Group, chaired by the Director of Health and included representatives from relevant medical specialties, the beauty industry and consumer groups, was tasked to differentiate high-risk medical procedures from low-risk, non-invasive beauty services, and

make recommendations on procedures that should be performed by registered medical practitioners. Three other working groups, which are respectively responsible for defining high-risk medical procedures/practices performed in an ambulatory setting, regulation of premises processing health products for advanced therapy, and regulation of private hospitals have also been set up under the Steering Committee.

4. The Working Group has met three times and examined the health risks of a list of 35 types of cosmetic procedures. The seven recommendations put forth by the Working Group, and the Administration's plan to implement these recommendations were endorsed by the Steering Committee on 1 November 2013.

Deliberations of the Panel

5. The Panel held two special meetings on 26 October and 27 November 2012 respectively to discuss regulation of medical beauty treatment/procedures and receive the views of deputations at the latter meeting. The Panel received a briefing by the Administration on the recommendations of the Working Group and the Administration's implementation plan at its meeting on 18 November 2013. The deliberations of the Panel are summarized below.

Differentiation between medical treatments and beauty services

6. Noting that some invasive procedures such as nose or tongue piercing and tattooing were commonly performed by beauty services companies, concern was raised as to whether invasiveness of procedures was a suitable criterion for differentiating medical treatments from beauty services, and the enforceability and practicability of the provisions if so provided. There was a view that the differentiation should take into account not only the risk level but also the providers of the procedures. Some members considered it necessary to provide a clear definition of medical treatment/procedure, and a classification system for medical treatments/procedures according to their invasiveness and risk level in order to map out the appropriate level of control. There was another view that all procedures that would pose a risk to infection or contracting certain diseases should be subject to statutory regulation. Any non-compliance should lead to prosecution, so as to prevent those unscrupulous service providers from evading their responsibility by closing down their businesses.

7. At the meeting on 18 November 2013, members were advised that the Working Group had recommended that cosmetic procedures involving

injections; mechanical or chemical exfoliation of the skin below the epidermis; hyperbaric oxygen therapy; and dental bleaching or teeth whitening should be performed only by registered medical practitioners or registered dentists due to their inherent risks. The Administration would follow up on these recommendations and take enforcement action as necessary under the Medical Registration Ordinance (Cap. 161) and the Dentists Registration Ordinance (Cap. 156). Taking into account that body tattooing and piercing which involved skin puncture and inject of pigment or insertion of objects into the skin were traditionally deemed non-medical procedures and their associated risks were already well known to the general public, it was recommended that these procedures should be exempt from being regarded as medical treatment. However, practitioners should ensure that customers were aware of the inherent risks and was allowed to make informed decisions before undergoing the procedures.

8. There was a call for the Administration to strengthen enforcement actions against persons who practised medicine/surgery or dentistry without registration. Some members urged the Administration to step up efforts to ensure that registered medical practitioners, in particular those associating with beauty service companies, would act in the patients' best interests when performing these procedures. The Administration advised that the Department of Health ("DH") would conduct market surveillance and collaborate with the Consumer Council to identify suspected violation of Cap. 161 or Cap. 156. It would also issue letters to registered medical practitioners and registered dentists reminding them to strictly observe the Code of Professional Conduct issued by their Councils when conducting cosmetic procedures in their professional practice.

9. Members noted that the Administration was separately planning on introducing a new piece of legislation to regulate medical devices, which covered, among others, cosmetic-related devices. There was a view that the Working Group's recommendations on the above four cosmetic procedures should not be taken forward until the review on medical devices was completed.

10. The Administration advised that the above recommendations were generally agreed by members of the Working Group. Their early implementation was of utmost importance to the protection of public health. The other two recommendations of the Working Group, which were mainly concerned with cosmetic procedures involving skin puncture and the use of energy-emitting devices (i.e. procedures involving microneedle therapy; Class 3B and 4 lasers; radiofrequency; intense pulsed light; extracorporeal shock wave; high intensity

focused and nonthermal ultrasound for lipolysis; cryolipolysis; high voltage pulsed current; plasma; lighting emitting diode phototherapy; infrared light; micro-current therapy; cryoelectrophoresis; electroporation/iontophoresis; pulsed magnetic field therapy; and microwave application) and were far more controversial, would be dealt with under the proposed medical device regulatory framework.

Regulation of cosmetic-related medical devices

11. Members noted that the regulatory approach to those cosmetic procedures involving the use of medical devices would be deliberated within the future regulatory framework for medical devices. They expressed concern that the new regulatory framework would have great impact on the development of the beauty industry as some cosmetic procedures involved the use of devices which emitted different forms of energy. There were views that over regulation would reduce consumer choice of affordable advanced cosmetic procedures.

12. The Administration advised that the regulation of medical devices involved complex issues as devices were heterogeneous by nature. Under the proposed regulatory framework, the level of control would be proportional to the degree of risk posed by a medical device to individual users and the public. Those cosmetic-related devices falling within the definition of "medical device" would be regulated under the proposed legislation. In view of the complexity of the issue and the rapid advances in technology, the Administration would engage an international authority as consultant to conduct more in-depth study into the regulatory framework of cosmetic-related medical devices.

13. Question was raised as to whether beauticians having undergone appropriate training would be allowed to operate the cosmetic-related medical devices under the new regulatory regime as long as they were working under the supervision of registered medical practitioners. The Administration explained that the employment of any person trained to perform specialized duties or functions in connection with the medical treatment of a patient was acceptable provided that the registered medical practitioner concerned exercised effective personal supervision over the persons so employed and retained personal responsibility for the treatment of the patients.

14. On the legislative timetable to introduce the regulatory framework, the Administration advised that it planned to report to the Panel on the way forward for the proposed regulation of medical devices in the first half of 2014. Taking into account the views of the Panel, the Administration would consult the public

on the proposed regulatory framework. After studying the views received in the public consultation exercise, the Administration would proceed with the drafting of the legislative proposal. Members strongly called on the Administration to engage the beauty industry in formulating the new regulatory regime for medical devices.

Regulation of beauty services companies and the beauty industry

15. At its meeting on 26 October 2012, the Panel passed a motion expressing serious disappointment that the Administration had failed to provide effective measures to ensure that the health and life of people receiving medical beauty therapy would not be threatened, and urging the Government to comprehensively review the medical beauty industry and expeditiously launch effective measures to safeguard the public, including introducing legislation and a licensing system to regulate the medical beauty industry.

16. Some members considered that in the absence of regulation over the operation of beauty services companies, the Administration's current proposal of identifying those high-risk cosmetic procedures that could only be performed by qualified personnel could not address the problem. They stressed the need to introduce more stringent control on the beauty services companies. The Administration advised that DH would issue an advisory note to the beauty service providers to advise them to refrain from performing the four procedures classified as medical treatment if they were not themselves registered medical practitioners or registered dentists. When they referred their clients to registered medical practitioners for service, the name of the medical practitioners should be made known to the client in writing.

17. While supporting the enhancement of regulation over high-risk cosmetic procedures for better protection of consumers undergoing cosmetic procedures, some members considered that due regard should be given to the impact of the enhanced regulation of these procedures and the use of energy-emitting devices on the livelihood of the frontline beauticians, many of whom had acquired recognition in respect of their expertise for performing certain advanced cosmetic procedures. The Beauty Industry Training Advisory Committee had also developed a set of Specification of Competency Standards ("SCS") to serve as a guide on the competency standards required of employees of the beauty industry at different levels under the Qualifications Framework ("QF"). The qualifications conferred by those SCS-based training programmes, if the quality of which was assured by the Hong Kong Council for Accreditation of Academic

and Vocational Qualifications, would be recognized under QF. In addition, a Recognition of Prior Learning mechanism was in place to enable employees of the beauty industry to seek formal recognition of the knowledge, skills and experience they acquired at the workplace. They relayed the view of the beauty industry that it was necessary for the Administration to formulate a regulatory regime for the profession in order to promote the sustainable development of the industry.

18. The Administration advised that instead of regulating the beauty industry indiscriminately, it had adopted a risk-based approach focusing on those procedures or treatments that were intrinsically risky and could cause considerable harm to clients if not properly administered by qualified personnel. The identification of the types of cosmetic procedures that could only be performed by registered medical practitioners or registered dentists, and the future introduction of a regulatory regime for medical devices would provide enhanced protection to consumers undergoing cosmetic procedures. The remaining practices of the beauty industry were non-intrusive and involved no or very little health risks that called for direct regulatory intervention. The Administration did not have any plan to put in place a separate regulatory framework for the beauty industry at this stage.

19. At its meeting on 18 November 2013, the Panel passed a motion urging the Government to set up a "Steering Committee on Regulation of Beauty Industry" to assist the beauty industry in formulating a comprehensive set of regulatory and training regime for the profession, so as to sustain the healthy development of the industry and enhance the competence of practitioners, in order to ensure the safety and confidence of people in using beauty services.

<u>Regulation of private healthcare facilities</u>

20. Members were generally of the view that the existing legislation in regulating private healthcare premises was far from effective in protecting public health. They noted that with the evolution of medical technology, some high-risk and complicated medical treatments/procedures which were previously performed in the hospital setting were currently performed at ambulatory medical centres and non-clinical facilities. However, these premises, as well as those laboratories set up in the community setting for the processing of health products for advanced therapies, were not covered in the existing regulatory framework of private healthcare premises. Members urged the Administration to expeditiously introduce a regulatory framework for these premises.

21. The Administration advised that the Steering Committee would, among others, examine the need to introduce a more comprehensive regulatory framework for the performance of high-risk medical treatments/procedures. It could not be ruled out that medical or clinical laboratories undertook aseptic work would be subject to licensing control in the future. Upon completion of the review, the Administration would consult the public on the proposals put forward by the Steering Committee.

Efforts to enhance the safety of beauty services

22. There were views that the Administration should proactively inspect those beauty services companies suspected of involving in the provision of high-risk medical treatments/procedures, step up public education on the risks associated with cosmetic procedures and how to select safe beauty services. Considering the large number of beauty services advertisements involving medical treatments/procedures in the printed media, members also expressed concern over the small number of successful prosecutions against beauty services companies under the Undesirable Medical Advertisements Ordinance (Cap. 231) between 2010 and 2012.

23. Members were advised that the Administration would step up public education to raise public awareness on the risks associated with cosmetic procedures via various media channels. A new television Announcement in the Public Interest had also been launched in late 2013. DH would enhance screening of advertisements of beauty services and work with the Consumer Council to analyze complaints, conduct inquiries, carry out proactive inspections and where necessary, take enforcement action against suspected violation of Cap. 161 or Cap. 156.

Unfair trade practices in respect of beauty services

24. Some members considered that consumers who were dissatisfied with the results of the beauty treatments/procedures received should be entitled to refund or compensation. In addition, a seven-day cooling-off period to cover consumer transactions involving beauty services should be introduced.

25. The Administration advised that during the public consultation on the legislative proposals to combat unfair trade practices from 2010 to 2011, the community widely discussed the issue of cooling-off period. While general consumers welcomed the proposal for a mandatory cooling-off period, the trades

expressed concern about the practical issues involved, such as the refund and cancellation arrangements. Meanwhile, the Trade Descriptions (Unfair Trade Practices) (Amendment) Ordinance 2012 ("the Amendment Ordinance") enacted by the Legislative Council in July 2012 had enhanced the scope of consumer protection by amending the Trade Descriptions Ordinance (Cap. 362) to extend its coverage to services (including beauty services), prohibit certain unfair trade practices and enhance enforcement mechanisms. The Administration would keep in view the implementation of the Amendment Ordinance and examine the need to introduce cooling-off arrangements as and when necessary.

Relevant papers

26. A list of the relevant papers on the Legislative Council website is in **Appendix**.

Council Business Division 2
Legislative Council Secretariat
19 December 2013

Appendix

Relevant papers on regulation of medical beauty treatments/procedures

Committee	Date of meeting	Paper
Panel on Health Services	26.10.2012 (Item I)	Agenda Minutes CB(2)143/12-13(01) CB(2)315/12-13(01)
	27.11.2012 (Item I)	Agenda Minutes CB(2)643/12-13(01)
	18.11.2013 (Item IV)	Agenda
Council meeting	31.10.2012	Motion on "Regulating beauty industry"
	19.6.2013	[Question 1] Asked by: Hon Vincent FANG Incidents relating to cosmetic procedures and surgical plastic operations

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